Amendments in the Claims

Claims 1 to 17 have been cancelled.

18. (Withdrawn) A method of delivering an active agent in vivo comprising administering to a subject a purified composition of claim 8.

19. (Withdrawn) A method of delivering a drug to a subject comprising administering to the subject a purified composition of claim 14.

20. (Withdrawn) A method of delivering a drug to a subject comprising administering to the subject a purified composition of claim 15.

21. (Withdrawn) The method according to claim 18 in which the administering is oral.

22. (Withdrawn) The method according to claim 18 in which the active agent is a drug.

23. (Withdrawn) The method according to claim 18 in which the subject is a human.

24. (Withdrawn) The method according to claim 21 in which the subject is a human.

25. (Withdrawn) The method according to claim 18 in which said composition facilitates the transport of the active agent through human or animal gastro-intestinal tissue.

26. (Withdrawn) The method according to claim 19 in which the administering is oral.

Claim 27 has been cancelled.

28. (Withdrawn) An antibody which is capable of immunospecifically binding the peptide of claim 1.

29. (Withdrawn) A molecule comprising a fragment of the antibody of claim 28, which fragment is capable of immunospecifically binding said peptide.

Claims 30 to 34 have been cancelled.

35. (Withdrawn) A method of treating or preventing a disease or disorder comprising administering to a subject in which such treatment or prevention is desired a therapeutically effective amount of the composition of claim 8.

36. (Withdrawn) A method of treating or preventing a disease or disorder comprising administering to a subject in which such treatment or prevention is desired a therapeutically effective amount of the composition of claim 14.

37. (Withdrawn) A method of treating or preventing a disease or disorder comprising administering to a subject in which such treatment or prevention is desired a therapeutically effective amount of the composition of claim 15.

38. (Withdrawn) The method according to claim 35 in which the disease or disorder is selected from the group consisting of: hypertension, diabetes, osteoporosis, hemophilia, anemia, cancer, migraines, and angina pectoris.

39. (Withdrawn) The method according to claim 38 in which the subject is a human.

Claims 40 to 43 have been cancelled.

44. (Withdrawn) A synthetic protein comprising a retroinverted peptide, said retroinverted peptide being the retro-inverted form of an L-peptide that has an amino acid sequence selected from the group consisting of SEQ ID NOS: 16-70, said synthetic protein being one that specifically binds to a Caco-2 cell membrane fraction.

45. (Withdrawn) A synthetic protein of claim 44 wherein the protein consists of not more than 75 amino acids.

46. (Withdrawn) A synthetic protein of Claims 44 wherein the protein is the retroinverted peptide.

47. (Withdrawn) A synthetic protein comprising either a retro-inverted peptide or fragment thereof, said retroinverted peptide being the retroinverted form of an L-peptide consisting of an amino acid sequence selected from the group consisting of SEQ ID NOS: 16-70, wherein said fragment has at least five contiguous amino acids and wherein said synthetic protein specifically binds to a Caco-2 cell membrane fraction.

48. (Withdrawn) A synthetic protein of Claim 47 wherein the fragment has at least 10 contiguous amino acids.

49. (Withdrawn) A synthetic protein of Claim 48 wherein the fragment has at least 20 contiguous amino acids.

50. (Withdrawn) A synthetic protein of claim 47, wherein the fragment consists of an amino acid sequence selected from the group consisting of:
(a) rtrlrrnhsshkant (SEQ ID NOA), which is the retro-inverted form of the L-peptide TNAKHSSHNRRLRTR (SEQ ID N0:4);
(b) gphrrgrpnsrsskrt (SEQ ID N0:2), which is the retro-inverted form of the L-peptide TRKSSRSNPRGRRHPG (SEQ ID N0:5); and
(c) gtsngngccnydgp (SEQ ID N0:3), which is the retro-inverted form of the L-peptide PGDYNCCGNGNSTG (SEQ ID N0:6).

51. (Withdrawn) A synthetic protein of Claim 50 wherein the synthetic protein is a fragment consisting of an amino acid sequence selected from the group consisting of:
(a) rtrlrrnhsshkant (SEQ ID N0:1), which is the retro-inverted form of the L-peptide TNAKHSSHNRRLRTR (SEQ ID N0:4);
(b) gphrrgrpnsrsskrt (SEQ ID N0:2), which is the retro-inverted form of the L-peptide TRKSSRSNPRGRRHPG (SEQ ID N0:5); and
(c) gtsngngccnydgp (SEQ ID N0:3), which is the retro-inverted form of the L-peptide PGDYNCCGNGNSTG (SEQ ID N0:6).

52. (Withdrawn) A synthetic protein of claims 47-50 wherein the synthetic protein consists of not more than 75 amino acids.

53. (Withdrawn) A synthetic protein of claims 47-50 wherein the synthetic protein consists of not more than 50 amino acids.

54. (Withdrawn) A synthetic protein comprising either a retro-inverted peptide or a homolog of said retro-inverted peptide, said retroinverted peptide being the retroinverted form of an Lpeptide that consisting of an amino acid sequence selected from the group consisting of SEQ ID NOS- 16-70,

wherein said homolog is based on percent homology or on amino acid functional equivalency,

wherein said synthetic protein specifically binds to a Caco-2 cell membrane fraction,

wherein a homolog based on percent homology is one that has at least 80 % but less than 100% identity with said retro-inverted peptide when the homolog is compared to a sequence of equal length of the retroinverted peptide, and

wherein a homolog based on amino acid functional equivalency is one that comprises one or more amino acid differences compared to the retroinverted peptide, and wherein each amino acid difference is consistent with the following rules:

1) a nonpolar amino acid is replaced by another nonpolar amino acid, wherein the nonpolar amino acids are alanine,leucine, isoleucine, valine, proline, phenylalanine, tryptophan and methionine;
2) a polar neutral amino acid is replaced by another polar neutral amino acid wherein the polar neutral amino acids are glycine, serine, threonine, cysteine, tyrosine, asparagine, and glutamine;
3) a positively charged amino acid is replaced by another positively charged amino acid wherein the positively charged amino acids are arginine, lysine, and histidine; and

4) a negatively charged amino acid is replaced by another negatively charged amino acid, wherein the negatively charged amino acids are aspartic acid and glutamic acid.

55. (Withdrawn) A synthetic protein of claim 54 wherein the homolog is based on percent homology.

56. (Withdrawn) A synthetic protein of Claim 55 wherein the homolog has at least 90 % but less than 100% identity with said retro-inverted peptide when the homolog is compared to a sequence of equal length of the retroinverted peptide.

57. (Withdrawn) A synthetic protein of Claim 54 wherein the homolog is based on amino acid functional equivalency.

58. (Withdrawn) A synthetic protein comprising either a retro-inverted peptide, a fragment of at least five contiguous amino acids of said retroinverted peptide, or a homolog of said fragment,

wherein said retroinverted peptide is the retroinverted form of an L-peptide consisting of an amino acid sequence selected from the group consisting of SEQ ID NOS 16-70,

wherein said homolog is based on percent homology or on amino acid functional equivalency,

wherein said synthetic protein specifically binds to a Caco-2 cell membrane fraction;

wherein said homolog has at least 80 % but less than 100% identity with said fragment when the homolog is compared to a sequence of equal length of the fragment, and

wherein a homolog based on amino acid functional equivalency is one that comprises one or more amino acid differences compared to the retroinverted peptide, and wherein each amino acid difference is consistent with the following rules:

1) a nonpolar amino acid is replaced by another nonpolar amino acid, wherein the nonpolar amino acids are alanine,leucine, isoleucine, valine, proline, phenylalanine, tryptophan and methionine;
2) a polar neutral amino acid is replaced by another polar neutral amino acid wherein the polar neutral amino acids are glycine, serine, threonine, cysteine, tyrosine, asparagine, and glutamine;
3) a positively charged amino acid is replaced by another positively charged amino acid wherein the positively charged amino acids are arginine, lysine, and histidine; and
4) a negatively charged amino acid is replaced by another negatively charged amino acid, wherein the negatively charged amino acids are aspartic acid and glutamic acid.

59. (Withdrawn) A synthetic protein of Claim 58 wherein the fragment has at least 10 contiguous amino acids.

60. (Withdrawn) A synthetic protein of Claim 59 wherein the fragment has at least 20 contiguous amino acids.

61. (Withdrawn) A synthetic protein of claim 58, wherein the fragment consists of an amino acid sequence selected from the group consisting of:
(a) rtrlrrnhsshkant (SEQ ID N0:1), which is the retro-inverted form of the L-peptide TNAKHSSHNRRLRTR (SEQ ID NOA);

(b) gphrrgrpnsrsskrt (SEQ ID N0:2), which is the retro-inverted form of the L-peptide TRKSSRSNPRGRRHPG (SEQ ID N0:5); and
(c) gtsngngccnydgp (SEQ ID N0:3), which is the retro-inverted form of the L-peptide PGDYNCCGNGNSTG (SEQ ID N0:6).

62. (Withdrawn) A synthetic protein of Claim 61 wherein the synthetic protein is a fragment consisting of an amino acid sequence selected from the group consisting of:
(a) rtrirrnhsshkant (SEQ ID N0:1), which is the retro-inverted form of the L-peptide TNAKHSSHNRRLRTR (SEQ ID N0:4);
(b) gphrrgrpnsrsskrt (SEQ ID N0:2), which is the retro-inverted form of the L-peptide TRKSSRSNPRGRRHPG (SEQ ID N0:5); and
(c) gtsngngccnydgp (SEQ ID N0:3), which is the retro-inverted form of the L-peptide PGDYNCCGNGNSTG (SEQ ID N0:6).

63. (Withdrawn) A synthetic protein of claim 58 wherein the protein consists of not more than 75 amino acids.

64. (Withdrawn) A synthetic protein of claim 63 wherein the protein consists of not more than 50 amino acids.

65. (Withdrawn) A synthetic protein of claim 58 wherein the homolog is based on percent homology.

66. (Withdrawn) A synthetic protein of Claim 65 wherein the homolog has at least 90 % but less than 100% identity with said retro-inverted peptide when the homolog is compared to a sequence of equal length of the retroinverted peptide.

67. (Withdrawn) A synthetic protein of Claim 58 wherein the homolog is based on amino acid functional equivalency.

68. (Withdrawn) A synthetic protein of not more than 50 amino acids comprising a retroinverted peptide, such retroinverted peptide being the retroinverted form of an Lpeptide consisting of an amino acid sequence selected from the group consisting of

(a) Xaa_1 Thr Xaa_2 Xaa_3 Ser Xaa_4 Xaa_5 Xaa_6 Asn Xaa_7Arg (SEQ ID NO: 71), where Xaa_1 is Ser or Thr; Xaa_2 is Arg or Lys; Xaa_3 is Lys or Arg; Xaa_4 is Ser or Leu; Xaa_5 is Arg, Ile, Val, or Ser; Xaa_6 is Ser, Tyr, Phe, or His; and Xaa_7 is Pro, His or Arg;

(b) Asp Xaa_1 Asp Xaa_2 Arg Arg Xaa_3 Xaa_4 (SEQ ID NO: 72) where Xaa_1 is Ser, Ala, or Gly; Xaa_2 is Val or Gin; Xaa_3 is Pro, Gly, or Ser; and Xaa_4 is Trp or Tyr;

(c) Val Arg Ser Gly Cys Gly Xaa_1 Xaa_2 Ser Ser (SEQ ID NO: 73), where Xaa_1 is Ala or Phe; and Xaa_2 is Arg or His;

(d) NTRKSSRSNPR (SEQ ID NO: 74);

(e) STKRSLIYNHR (SEQ ID NO: 75);

(f) STGRKVFNRR (SEQ ID NO: 76);

(g) TNAKHSSHNRR (SEQ ID NO: 77);

(h) DSDVRRPW (SEQ ID NO: 78);

(i) AADQRRGW (SEQ ID NO: 79);

(j) DGRGGRSY (SEQ ID NO: 80);

(k) RVRS (SEQ ID NO: 81);

(l) SVRSGCGFRGSS (SEQ ID NO: 82);

(m) SVRGGCGAHSS (SEQ ID NO: 83);

wherein said synthetic protein specifically binds to CaCo-2 cell membrane fraction.

69. (Withdrawn) The synthetic protein of claim 68 wherein the selected amino acid sequence is SEQ ID NO: 71.

70. (Withdrawn) The synthetic protein of claim 68 wherein the selected amino acid sequence is SEQ ID NO: 72.

71. (Withdrawn) The synthetic protein of claim 68 wherein the selected amino acid sequence is SEQ ID NO: 73.

72. (Withdrawn) The synthetic protein of claim 68 wherein the amino acid sequence is selected from the group consisting of SEQ ID NOS: 74-77.

73. (Withdrawn) The synthetic protein of claim 68 wherein the amino acid sequence is selected from the group consisting of SEQ ID NOS: 78-80.

74. (Withdrawn) The synthetic protein of claim 68 wherein the amino acid sequence is selected from the group consisting of SEQ ID NOS: 81-83.

75. (Withdrawn) A synthetic protein of claims 44, 47, 54, 58, or 68 wherein one or more amino acids of the retroinverted peptide, fragment, or homolog thereof, has undergone derivatization selected from the group consisting of glycosylation, acetylation, phosphorylation,amidation and
wherein said homolog that has undergone derivatization binds specifically binds to a Caco-2 cell membrane fraction.

76. (Withdrawn) A composition comprising the synthetic protein of Claims 44, 47, 54, 58, or 68, wherein the synthetic protein is coated onto or absorbed onto or covalently bonded to the surface of a nanoparticle or microparticle.

77. (Withdrawn) A compostion of Claim 76 wherein the particle size of the nanoparticle or microparticle is between 10 nm and 500 pm.

78. (Withdrawn) A composition of Claim 76 wherein the nanoparticle or microparticle is a drug-loaded or drug-encapsulating nanoparticle or microparticle.

79. (Withdrawn) A composition comprising both a synthetic protein of Claims 44, 47, 54, 58 or 68, and a material comprising a drug.

80. (Withdrawn) A composition of Claim 79 wherein the material is a slow-release device.

81. (Withdrawn) A composition of Claim 79 wherein the synthetic protein is covalently bound to the material.

82. (Withdrawn) A composition of Claim 79 wherein the synthetic protein is non-covalently bound to the material.

83. (Withdrawn) A composition of Claim 78 wherein the drug is selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-migraine agent, an anti-coagulant agent, a cardiovascular agent, and anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a

chemotherapeutic agent, a sedative, an antineoplastic agent, a prostoglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene- correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNA-modifying agent, a non-viral gene delivery system, and a viral vector gene system.

84. (Withdrawn) A composition of Claim 78 wherein the drug is selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, a-interferon, p-interferon, y-interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activatgor, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin, hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

85. (Withdrawn) A composition of Claim 78 wherein the drug is insulin or leuprolide.

86. (Withdrawn) A composition of Claim 79 wherein the drug is selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-

migraine agent, an anticoagulant agent, a cardiovascular agent, and anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a chemotherapeutic agent, a sedative, an anti-neoplastic agent, a prostoglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene- correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNA-modifying agent, a non-viral gene delivery system, and a viral vector gene system.

87. (Withdrawn) A composition of Claim 79 wherein the drug is selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, a-interferon, P-interferon, y-interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activatgor, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin, hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

88. (Withdrawn) A composition of Claim 79 wherein the drug is insulin or leuprolide.

89. (New) A retro-inverted peptide comprising amino acid residues that specifically binds to a gastro-intestinal tract receptor selected from the group consisting of HPT1 (human intestinal oligopeptide transporter), hPEPT1 (human oligopeptide transporter), D2H (human D2 clone), and hSI (human sucrase isomaltose).

90. (New) The retro-inverted peptide of claim 89, wherein the peptide comprises an amino acid sequence selected from the group consisting of ZElan144 (SEQ ID NO:1), ZElan 145 (SEQ ID NO:2), and ZElan 146 (SEQ ID NO:3).

91. (New) A retro-inverted peptide that enhances delivery of an active agent across the gastro-intestinal tract into the systemic, portal or hepatic circulation.

92. (New) The peptide of claim 89, wherein the peptide comprises no more than 50 amino acid residues.

93. (New) The peptide of claim 89, wherein the peptide comprises no more than 40 amino acid residues.

94. (New) The peptide of claim 89, wherein the peptide comprises no more than 30 amino acid residues.

95. (New) The peptide of claim 89, wherein the peptide comprises no more than 20 amino acid residues.

96. (New) A composition comprising the peptide of claim 89 bound to a material comprising an active agent, said active agent being of value in the treatment of a mammalian disease or disorder.

97. (New) The composition of claim 96 wherein the active agent is a drug.

98. (New) The composition of claim 96 wherein the material is a particle containing an active agent.

99. (New) The composition of claim 96 wherein the material is a slow-release device containing the drug.

100. (New) The composition of claim 96 wherein the peptide is covalently or non-covalently bound to the material.

101. (New) A composition comprising a chimeric protein bound to a material comprising an active agent, in which the chimeric protein comprises a sequence selected from the group consisting of ZElan144 (SEQ ID NO:1), ZElan 145 (SEQ ID NO:2), and ZElan 146 (SEQ ID NO:3) or a binding portion thereof fused via a covalent bond to an amino acid sequence of a second protein, in which the active agent is of value in the treatment of a mammalian disease or disorder.

102. (New) A composition comprising the peptide of claim 89 non-covalently bound to a particle containing a drug.

103. (New) A composition comprising the peptide of claim 89 covalently bound to a drug.

104. (New) The composition of claim 96 which increases the transport of the active agent through human or animal gastro-intestinal tissue.

105. (New) The composition of claim 96 which targets the active agent to a selected site or selected tissue in a human or animal.

106. (New) A pharmaceutical composition comprising the composition of claim 96 in a pharmaceutically acceptable carrier suitable for use in humans *in vivo*.

107. (New) A pharmaceutical composition comprising a therapeutically effective amount of a composition comprising the peptide of claim 89 and a pharmaceutically acceptable carrier.

108. (New) A composition comprising the peptide of claim 89, wherein he peptide is coated onto or absorbed onto or covalently bonded to the surface of a nanoparticle or microparticle.

109. (New) A nanoparticle or microparticle formed from the peptide of claim 89.

110. (New) The composition of claim 112, wherein the nano- or microparticle is a drug-loaded or drug-encapsulating nanoparticle or microparticle.

111. (New) The composition of claim 96 wherein the drug is insulin or leuprolide.

112. (New) The composition of claim 96 wherein said mammalian disease or disorder is selected from the group consisting of hypertension, diabetes, osteoporosis, hemophilia, anemia, cancer, migraine, and angina pectoris.

113. (New) The composition of claim 101 wherein said mammalian disease or disorder is selected from the group consisting of hypertension, diabetes, osteoporosis, hemophilia, anemia, cancer, migraine, and angina pectoris.